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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,389	12/18/2001	Georges Natsoulis	0800-0005.04	1714

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	4

DATE MAILED: 05/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,389	Applicant(s) NATSOULIS ET AL
	Examiner Maria B. Marvich	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other.

DETAILED ACTION

Specification/Informalities

The disclosure is objected to because of the following informalities: A large blank section appears in the specification at page 8.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3-7, 9-12, 14, 16 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of prior U.S. Patent No. 6,027,931. This is a double patenting rejection.

Claims 5-6 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 of prior U.S. Patent No. 6,365,403. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 8, 13 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,027,931. Although the conflicting claims are not identical, they are not patentably distinct from each other because while both sets of claims recite the same methods and host cells for the production of rAAV, the instant application also claims the rAAV in claims 2, 8, 13, 15. Therefore, while the claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter is encompassed within the claims of the 6,027,931 patent. It would have been obvious to one of ordinary skill to take the claims from patent 6,027,931 to generate the instant invention because the same methodologies for producing rAAV is recited in both. The ordinary skilled artisan would have been motivated to also claim the rAAV produced by the methodology due to the success recited in the claims of US patent 6,027,931 of efficiently producing the rAAV. Given the teachings of the claims in 6,027,931 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for rAAV production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,027,931 patent, then two different assignees would hold a patent to the claimed invention of 6,027,931, and thus improperly there would be possible harassment by multiple assignees.

Claims 12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of U.S. Patent No. 6,365,403. Although

the conflicting claims are not identical, they are not patentably distinct from each other because claims 7-10 in 6,365,403 claim the same compositions i.e. host cell comprised of an AAV helper function vector for the production of small amounts of long forms of Rep protein claimed in the method claims for the production rAAV of the instant application. Therefore, while the claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter is encompassed within the claims of the 6,365,403 patent. It would have been obvious to one of ordinary skill to take the claims from patent 6,365,403 to generate the methodologies for producing rAAV recited in the instant application as the host cells of 6,365,403 patent were designed for said methodology. The ordinary skilled artisan would have been motivated to utilize the method of producing rAAV utilizing the host cells due to the success of utilizing the host cells for "producing high titer preparations of rAAV virions" (abstract) that are recited in the claims of US patent 6,365,403. Given the teachings of the claims in 6,365,403 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for rAAV production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,365,403 patent, then two different assignees would hold a patent to the claimed invention of 6,365,403, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 2, 8, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Shenk **et al** (US Patent 5,436,146). Shenk et al claim a "helper free stock of rAAV" (claim 12) generated with a recombinant helper AAV DNA in combination with a rAAV vector comprised of up to 195 base pairs of the AAV ITRs (pAAV/neo, figure 1A). It is disclosed that this includes the entire 145 bp terminal repeats of the AAV genome containing the cis-acting signals needed to achieve excision and replication (col 21, line 36-39). In the instant application, a rAAV virion is defined (column 8, line 16-20) as an infectious, replication-defective virus composed of an AAV protein shell encapsulating a heterologous nucleotide sequence of interest that is flanked on both side by AAV ITRs. While the rAAV of Shenk et al is produced by slightly different methods from that of the instant application; the resulting product, absent evidence to the contrary, does not differ from that in Shenk **et al** (see MPEP 2113).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to patent analyst Kay Pinkney whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
Art Unit 1636

May 16, 2002

DAVID GUZO
PRIMARY EXAMINER